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10/613,794	07/02/2003	Guy Vanney	0B-044900US-82410.0195	7352
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SJM/AFD-WILEY 14901 DEVEAU PLACE MINNETONKA, MN 55345-2126			EXAMINER PEFFLEY, MICHAEL F	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/613,794	Applicant(s) VANNEY, GUY	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/25/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

Applicant's amendments and comments, received June 25, 2008, have been fully considered by the examiner now of record. The following is a complete response to the June 25, 2008 communication.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Swanson et al (6,001,093).

As shown in Figures 40-45, Swanson et al disclose an ablation device comprising a tubular body (200) having a circumference and a distal end region, the tubular body having a partial curve that is adapted to change (see Figure 40). At least one ablating electrode (202) is provided along the curve and changes curve along with the tubular body (Figure 40). The electrode is configured to be flexible and to extend around only a portion of the circumference of the tubular body (see cross-sections of Figures 41A/B, 42A/B and 45). Figure 45 is deemed to read on a "saw-tooth" pattern given the peaks and valleys created by the electrode, and the electrode extend along the radius of the curve as shown in Figure 40.

Claims 1, 3-6 and 12-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kordis (5,499,981).

Kordis discloses an ablation catheter that comprises a tubular body (98 – Figures 32 to 42) that defines a curve (shown in Figure 38). The curve may change curvature depending on the amount of extension of the basket member. A plurality of ablating electrodes (96) are disposed along the curved body with the electrodes conforming to the curved shape of the body. The electrodes extend around only a portion of the circumference of the tubular body (see Figures), and are formed by interlaced strands that are exposed intermittently along the length of the curved region.

Claim Rejections - 35 USC § 103

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al ('093) as applied to claim 1 above, and further in view of Maschino et al (US 6600956 B2).

Swanson discloses the ablation catheter of claim 1 wherein the electrode is biasedly coupled with the at least partial curve along the distal end region of the tubular body (Figure 40), and wherein the biased connection is biased to change the curvature of the at least partial curve along the distal end region of the tubular body. Swanson et al do not disclose an elastically deformable electrode. Maschino teaches that it is known in the medical art to form electrodes so they are elastically deformable (column 4 lines 11-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Swanson et al by making the electrodes elastically deformable so that the electrode can stretch under small stresses in order to facilitate the curving of the tubular member.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (6,001,093).

Swanson et al do not specifically show a closed loop or open loop structure associated with the embodiment of Figures 40-45. However, earlier embodiments (Figure 27) clearly show that Swanson et al intended to create a wide range of shapes including open and closed loops. The examiner maintains that making any desired loop shape with the embodiment shown in Figures 40-45 would have been an obvious design consideration for the skilled artisan, particularly since Swanson et al clearly teach that such shapes are contemplated.

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al ('093) as applied to claim 1 above, and further in view of Kordis (5,499,981).

Swanson et al fail to disclose an interlaced electrode as set forth in these claims. Kordis discloses another ablation catheter that includes a tubular body (98) having electrodes (92) extending along a curved length of the tubular body. The electrodes are strands that are interlaced along the length of the tubular member to create An intermittently exposed series of electrodes. It is noted that Swanson et al also disclose the use of intermittent electrodes to create different lesion patterns.

To have provided the Swanson et al device with an interlaced series of electrodes to provide a flexible pattern of electrodes extending along a flexible tubular

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body would have been an obvious design choice for one of ordinary skill in the art in view of the teaching of Kordis.

Claims 1, 3-6, 10, 11, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al (6,171,306) in view of the teaching of Swanson et al (6,001,093).

Regarding claim 1, Swanson discloses an ablation catheter (12) comprising: a tubular body (flexible body, 42, Fig 6) having a distal end region, the tubular body defining at least a partial curve along the distal end region of the tubular body (see Fig 6), the partial curve being adapted to change curvature (via steering mechanism 18, column 7 lines 31-35); and at least one electrode (44) arranged along the at least partial curve (Fig 6), the at least one ablating electrode being adapted to change curvature along with the at least partial curve along the distal end region of the tubular body (column 7 lines 54-57 and column 8 lines 7-11), wherein the at least one electrode is configured to be flexible and resilient (column 7 lines 26-57). Swanson ('306) fails to disclose an electrode that extends around only a portion of the circumference of the tubular body. Swanson et al ('506) disclose substantially the same system, and further teach that it is known to provide an electrode on only a portion of the circumference of the tubular body, the electrode being provided on the flexible portion of the catheter. Specifically, Figures 40-42 show an embodiment with one or more electrodes (202) disposed along a curved length of the catheter, the electrode being formed around only a portion of the circumference of the catheter body (see cross sectional views). Figures

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43 and 45 disclose alternative embodiments of electrodes extending around only a portion of the circumference of a catheter in the curved region. To have provided the Swanson electrode as a series of longitudinally extending electrodes as taught by Swanson et al ('093) is deemed an obvious design modification, particularly since Swanson et al ('093) discloses a substantially identical device for the same purpose.

Regarding claim 3, Swanson discloses the ablation catheter of claim 1 further comprising a flexible and resilient shaping element (26).

Regarding claim 4, Swanson discloses the ablation catheter of claim 1 wherein the at least one flexible and resilient electrode is comprised, at least partially, of material selected from the group consisting of platinum, gold, stainless steel, and composite of conductive polymer metal (column 7 lines 38-40).

Regarding claim 5, Swanson discloses the ablation catheter of claim 1 wherein the at least one electrode strand defines a saw tooth pattern (formed by the cylindrical wire being wound around the tubular body; see Figs 6, 7A and 9).

Regarding claim 6, Swanson discloses the ablation catheter of claim 1 wherein the at least partial curve defines an outside radius (inherent with a curved tube), and wherein the at least one electrode defines a first end region and a second end region, and wherein the first end region is coupled with a point along the outside radius of the at least partial curve and wherein the second end region is coupled with a second point along the outside radius of the at least partial curve along the distal end region of the tubular body (see Figs 6 and 10).

Regarding claim 10, Swanson discloses the ablation catheter of claim 1 wherein the at least partial curve along the distal end region of the tubular body defines a closed loop (Fig 17B).

Regarding claim 11, Swanson discloses the ablation catheter of claim 1 wherein the at least partial curve along the distal end region of the tubular body defines an open loop (Fig 17A).

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson ('306) and Swanson ('093) as applied to claim 1 above, and further in view of Maschino et al (US 6600956 B2).

Swanson discloses the ablation catheter of claim 1 wherein the electrode is biasedly coupled with the at least partial curve along the distal end region of the tubular body (Figs 6 and 7A-8B), and wherein the biased connection is biased to change the curvature of the at least partial curve along the distal end region of the tubular body (Fig 6). Swanson does not disclose an elastically deformable electrode. Maschino teaches that it is known in the medical art to form electrodes so they are elastically deformable (column 4 lines 11-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Swanson by making the electrodes elastically deformable so that the electrode can stretch under small stresses in order to facilitate the curving of the tubular member.

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson ('306) and Swanson et al ('093) as applied to claim 1 above, and further in view of Kordis (5,499,981).

Swanson ('306) and Swanson et al fail to disclose an interlaced electrode as set forth in these claims. Kordis discloses another ablation catheter that includes a tubular body (98) having electrodes (92) extending along a curved length of the tubular body. The electrodes are strands that are interlaced along the length of the tubular member to create An intermittently exposed series of electrodes. It is noted that Swanson et al also disclose the use of intermittent electrodes to create different lesion patterns.

To have provided the Swanson device, as modified by the teaching of Swanson et al, with an interlaced series of electrodes to provide a flexible pattern of electrodes extending along a flexible tubular body would have been an obvious design choice for one of ordinary skill in the art in view of the teaching of Kordis.

Response to Arguments

Applicant's arguments filed on June 25, 2008 have been considered but are moot in view of the new ground(s) of rejection.

In particular, the examiner now of record has found and applied new prior art deemed to read on the amended claim language. It is noted that applicant has not substantively argued the obviousness rejections of claims 7-9 other than to assert that the prior art did not meet the limitation of amended claim 1. In as much as a new grounds of rejection has been made, as required by applicant's amendment, this new combination is also deemed tenable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/
Primary Examiner, Art Unit 3739

/mp/
October 28, 2008